TAMPER EVIDENT VIAL CAP AND INTEGRITY ASSURANCE METHOD

FIELD OF THE INVENTION

[0001] The invention relates to tamper evident vials and caps therefor, and to a method for assuring the integrity of specimen collection.

BACKGROUND OF THE INVENTION

[0002] Employers, government agencies, sports teams and other organizations have become increasingly involved in diagnostic testing to maintain safety in the workplace and to assure compliance with laws, rules and regulations. The presence of a predetermined analyte (e.g. drugs and/or disease) is determined by collecting biological fluids, i.e., urine, blood, sputum, pleural, cavity and peritoneal cavity fluids, for analysis. It is often vital in conducting such tests to maintain the integrity of the collected biological fluid specimens by minimizing or eliminating any potential for specimen contamination and/or by preserving the chain of custody.

[0003] There are many and varied known devices for collecting specimens. A particular device consists of a vial fitted with a heavy-duty screw cap attached to the vial with a tether. The integrity of the device depends on a plastic, easily broken, thus tamper evident, tape that is sealed across the cap and vial. When the specimen is collected, the donor can see that the tape is unbroken, which remains unbroken until the screw cap is removed in the donor's presence. The specimen is then placed in the tube, the cap replaced and the capped tube is shipped to a testing lab.

[0004] There are a number of deficiencies in such a system, one of which being that once the tape is broken, there is no longer any tamper evident mechanism, and the chain of custody must be maintained by other means, for example by affidavits and/or testimony. Another deficiency is that if care is taken by someone dedicated to the task, such a tape seal can be removed to unscrew the cap, and then the cap and tape can be replaced without the tampering being evident. Particularly for demonstrating integrity and chain of custody in drug testing, there is a need for a reliable mechanism that enables the donor of the specimen to be assured not only that

the container for the specimen is uncontaminated, but to also assure that it is sealed against contamination when shipped to a testing laboratory.

BRIEF SUMMARY OF THE INVENTION

[0005] The present overcomes the foregoing deficiencies by providing a tamper evident cap assembly of special construction, more particularly a combination of vial and cap assembly, assures the integrity of a specimen and of the specimen collection process. In accordance with one aspect of the invention, the cap is locked to the vial, when the vial is empty, with one of two latches that are integral to the cap assembly. The lock is broken in the presence of the specimen donor or in the presence of a witness who can testify as to chain of custody. A specimen is placed in the vial, following which the cap is locked to the vial with the other of the two latches also in the presence of the specimen donor or in the presence of a witness who can testify as to chain of custody. The second latch is broken when received by a testing laboratory.

[0006] In a particular embodiment, the vial is provided with a screw thread top and the tamper evident cap can be screwed onto the vial. A loop formed to encircle the vial is connected by a tether to the cap and slipped onto the vial. At least one restraining rib on the vial is spaced below the screw thread top and is sized to permit the loop to be forced upwardly thereover to be restrained from downward movement. In addition, at a limiting circumferential flange on the vial is spaced below the screw thread and above the loop restraining rib sufficient to accommodate the loop, and is sized to limit upward movement of the loop.

[0007] The two latches are each capable of locking the cap to the vial, each latch having a component extending from the loop and a corresponding component extending from the cap lockable to the loop component when the cap is screwed onto the vial, preferably irreversibly lockable. In a particular embodiment, one of the components of each latch is a latch staple and the corresponding locking component of each of said latches is a hasp. In a more specific embodiment, latch staples extend from the cap which can be inserted into, and lock with, respective hasps extending from the loop.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] For a more complete understanding of the present invention, reference is now made to the following descriptions taken in conjunction with the accompanying drawing, in which:

[0009] Figure 1 is a perspective, exploded view of a specimen vial and tamper evident cap, showing the cap and its tether loop in position to be assembled, the cap being formed with a pair of latch staples, the tether loop being formed with a pair of corresponding female hasps;

[0010] Figure 2 is a plan view of the cap and its tether loop;

[0011] Figure 3 is an elevational view of the cap and its tether loop;

[0012] Figure 4 is a detailed elevational view of the vial screw thread;

[0013] Figure 5 is a perspective view of the specimen vial and tamper evident cap, showing the cap and its tether loop assembled and ready to be closed;

[0014] Figure 6 is a detailed perspective view of one of the tether loop hasps;

[0015] Figure 7 is a detailed perspective view of one of the cap latch staples;

[0016] Figure 8 is a detailed elevational view of the cap - tether ring - vial screw thread, showing movement of one of the hasps into locking engagement with the corresponding latch staple to lock the cap to the vial;

[0017] Figure 9 is a perspective view of the cap - tether ring - vial screw thread, showing one of the hasps locked onto the corresponding latch staple, locking the cap to the vial;

[0018] Figure 10 is a perspective view of the cap - tether ring - vial screw thread of Figure 9 but wherein the cap and tether ring have been rotated so that the threads cause separation thereof and breaking of the latch - hasp connection of Figure 9; and

[0019] Figure 11 is a cross-sectional view of the cap - tether ring - vial screw thread after breaking the latch - hasp connection as in Figure 10, wherein the cap has been re-screwed onto the vial threads and the remaining hasp moved into locking engagement with the remaining latch staple to re-lock the cap to the vial.

DETAILED DESCRIPTION OF THE INVENTION

[0020] Referring to Figures 1 - 4, a combination of vial 10 and tamper evident cap assembly 12 are provided. Except as described below, the vial 10 has generally a

known construction for a specimen vial formed with a screw thread top 14. The vial 10 can be provided with an octagon - shaped bottom 16 to fit into an automatic analyzer, but that is not itself part of the invention. The cap assembly 12 consists of a heavy-duty screw cap 18 to which a retaining loop is connected by a tether 22. Except for the latching components described below, the cap – tethered loop assembly 12 also has generally a known construction.

[0021] In accordance with the invention, the cap assembly and vial are each modified from the prior art to provide locking latches that enable the combination to be tamper evident and to provide a unique method of assuring the integrity and chain of custody of specimen collection. In particular, the retaining loop 20 is provided with a pair of hasps 24 and 26 and the cap 18 is provided with corresponding latch staples 28 and 30, each of which are described in more detail below. The vial 10 is modified by providing with restraining ribs 32 around the circumference of the vial 10 spaced below the screw thread top 14 and which are sized to permit the loop 20 to be forced upwardly thereover to be restrained from downward movement. In addition, a limiting circumferential flange 34 (see particularly Figure 4) on the vial is spaced below the screw thread 14 and above the loop restraining ribs 32 sufficient to accommodate the loop 20, and is sized to limit upward movement of the loop 20.

[0022] Dimensions for a specific implementation are given in Figures 2, 3 and 4. It will be appreciated that alternative structures can be provided for the ribs 32 and for the flange 34. In place of a plurality of ribs 32 , one can use even a single rib, or single flange. Similarly, the circumferential flange 34 can be replaced by one or more ribs.

[0023] The assembled combination of vial 10 and tamper evident cap assembly 12 is shown in Figure 5 wherein the vial 10 has been inserted into the loop 20 which has been forced upwardly over the ribs (not shown in Figure 5) and secured between the ribs and the flange 34. Though secured, the loop 20 is free to rotate, so that the cap 18 can be screwed onto the screw thread top 14 of the vial 10.

[0024] The hasps 24 (not shown in Figure 5) and 26 and corresponding latch staples 28 and 30 fit together in such manner as to provide irreversibly locked latches. One of the hasps, 30, extending from the loop 20 is shown in detail in Figure 6 and is formed with a central slot 36, relieved sections such as at 38 and 40, and a thinned

neck 42 serving as an easily breakable line of weakness. One of the latch staples, 44, extending from the open edge of the cap 18 is formed in the shape of a double hook, formed with lines of weakness that serve to enable the staple 44 to bend to be inserted into the central hasp slot 36, and which also serve to enable the staple to be easily broken.

[0025] The manner by which one of the latch staples 28 is locked into a corresponding hasp 24 is shown in Figures 8 and 9. After the loop 20 is secured between the ribs 32 and flange 34, cap 18 is screwed clockwise onto the vial 10, the loop 20 turning with it via the tether 22 (Figure 9). When the cap 18 is fully secured on the vial 10, the hasp 24 is rotated upwardly, as schematically shown, until the hook end of the staple 44 is forced into the central slot 36 of the hasp 24. The cap 18 is now irreversibly locked to the vial 10. As such it can be shown to the specimen donor, or a witness who can testify as to chain of custody, providing assurance that the vial is uncontaminated.

[0026] Referring to Figure 10, to break the lock, also in the presence of the specimen donor or witness, one merely has to turn the cap 18 counterclockwise whereupon as the cap 18 rises on the vial screw top threads 14, the latch formed by the locked together staple 28 and hasp 24 (not shown in Figure 10) is stretched until one or both of the staple and hatch components breaks. In Figure 10, the hasp 24 has broken away, allowing the cap 18 to be removed.

[0027] A specimen is placed in the vial, following which the cap is locked to the vial with the other of the two latches, as shown in Figure 11, formed by inserting the remaining staple 30 into the remaining hasp 26, also in the presence of the specimen donor or in the presence of a witness who can testify as to chain of custody. The vial containing the specimen is then sent to a testing laboratory where the second locked latch is broken, which also can be in the presence of a witness who can testify as to chain of custody.

[0028] In practice, there will often be two vial-cap assembly combination so that the specimen can be shipped to two laboratories for redundant testing, or a specimen can be retained to be shipped to a second laboratory in the event that the test is positive. Alternatively, one of the specimens can be retained as evidence for

subsequent comparison to the shipped specimen. By providing an irreversibly locked latch, the integrity of the retained specimen is assured.

[0029] Although the present invention and its advantages have been described in detail, it should be understood that various changes, substitutions and alterations can be made herein without departing from the spirit and scope of the invention as defined by the appended claims. Moreover, the scope of the present application is not intended to be limited to the particular embodiments described in the specification. As one of ordinary skill in the art will readily appreciate from the disclosure of the present invention, means and methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized according to the present invention. Accordingly, the appended claims are intended to include within their scope such means, methods, and steps.